

Docket 6514-11-RMM

Claim 1-21, 24, 25 and 29-33 are pending. The invention is currently limited to an HPMC capsule with a single coating. While the "consisting essentially of" language makes this clear, the Examiner appears to still have some concerns and it is possible that an alternative wording change may be more acceptable to the Examiner, such as adding the phrase "wherein the coating consists essentially of a single coating". Such an invention is clearly outside the scope of Hatano et al (EP 0 754 452 A2) ("HATANO") and Watts (WO 95/35100) ("WATTS") as explained below.

In the Office Action, the Examiner rejects Claims 1-5, 7-10, 13-21, 24, 25 and 29-33 under 35 USC 103(a) on the basis of HATANO. This rejection is traversed. The Examiner maintains that HATANO can be limited to a single coating. This is a serious error and is not supported by HATANO. It is important that HATANO teaches away from single coated products. See, for example, Paragraphs numbers [0004], [0008] and , [0009]. HATANO distinguishes its products over the art by using two coatings. The following excerpts from HATANO clearly show that the HATANO requires at least two coatings.

[0016] In accordance with the present invention, there is provided a pharmaceutical preparation in the form of a coated capsule which can release contents of a capsule at a lower part of the digestive tract comprising (a) a hard capsule containing at least an acidic substance, (b) a polymer film soluble at low pH which is formed on a surface of said hard capsule, and (c) an enteric coating film which is formed on a surface of said polymer film soluble at low pH. . . .

[0043] The polymer soluble at low pH used for the pH-soluble polymer . . . can be a film-formable polymeric substance which is soluble at the acidic range . . .

[0058] As the combination of each polymer of the low pH-soluble polymer film and the enteric coating film in the present invention, the . . . polymers mentioned above are selected and used with taking into account the predetermined lag-time, the properties of the hard capsule, the kind of acidic substance and the like.

Thus, HATANO does not teach or suggest the ability to use the single coat described in the present invention. Moreover, HATANO describes the failure of single coated products to work and describes its technology as an improvement over single coated products.

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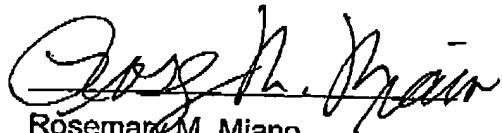
In the Office Action the Examiner rejects Claims 6, 11 and 12 under 35 USC 103(a) on the basis of HATANO in view of WATTS. This rejection is traversed for the reasons described above for HATANO and further in view of the limitation of WATTS to starch capsules (see WATTS at page 4, lines 4-17). WATTS does not include either HPMC or gelatin capsules in its invention. In fact, WATTS goes to great lengths to explain in particular why gelatin capsules do not work in the invention. Use of the starch material is problematic and a starch capsule is not interchangeable with an HPMC capsule. Such starch products are injection molded and do not have the same flexibility as an HPMC capsule. WATTS only teaches injection molded starch capsules. Also, all of the examples of WATTS teach the use of a "pre-coat" or "subcoat" to the starch capsule substrate prior to application of the functional colonic coating. This follows accepted practice in the pharmaceutical industry of providing a subcoat to allow the final functional coat to bind more effectively to the surface of the subcoat. WATTS does not teach either (i) an HPMC capsule or (ii) coating an HPMC capsule with a single aqueous coating. Additionally, as previously noted above, none of the examples of WATTS describe a capsule with a single coating or how that could be accomplished.

In conclusion, neither HATANO nor WATTS, alone or in combination, teach or suggest the claimed invention. It is respectfully submitted that the rejections have been overcome for the reasons explained above and on the basis of the Amendment listed herein. An early Notice of Allowability is respectfully requested.

The Examiner is requested to call the undersigned attorney to further discuss the case. A voice mail was left for the Examiner today. If agreement cannot be reached, a Notice of Appeal will be filed to have the case subjected to further review.

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Respectfully submitted,



Rosemary M. Miano
Attorney for Applicants
Reg. No. 29,674

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Warner-Lambert Company
201 Tabor Road
Morris Plains, New Jersey 07950
Phone (973) 385-6418
Fax (973) 385-3117
CUSTOMER NO. 29668